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*Actavis Pharma, Inc. and Actavis, Inc.*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

HORIZON PHARMA, INC. and POZEN  
INC.,

Plaintiffs,

Vs.

ACTAVIS LABORATORIES FL., INC.,  
ACTAVIS PHARMA, INC., and ACTAVIS  
INC.,

Defendants.

Civil Action No. 3:15-cv-03322-MLC-DEA

**DEFENDANTS' ANSWER, DEFENSES  
AND COUNTERCLAIMS TO FIRST  
AMENDED COMPLAINT FOR  
PATENT INFRINGEMENT**

**ANSWER TO FIRST AMENDED COMPLAINT**

Defendants Actavis Laboratories FL, Inc., Actavis Pharma, Inc., and Actavis, Inc. (collectively, “Actavis” or “Defendants”) hereby answer the First Amended Complaint of Plaintiffs Horizon Pharma, Inc. and Pozen Inc. (collectively, “Plaintiffs”), as follows:

**THE PARTIES**

1. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

2. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

3. Defendants admit that Actavis Laboratories FL, Inc. was formerly known as Watson Laboratories, Inc. - Florida, admit that Watson Laboratories, Inc. – Florida was formerly known as Andrx Pharmaceuticals, admit that Actavis Laboratories FL, Inc. is a Florida corporation having a place of business at 4955 Orange Drive, Davie, Florida 33314, and admit that Actavis Laboratories FL, Inc. is in the business of, among other things, developing, manufacturing, and obtaining regulatory approval of generic pharmaceutical products for the United States market. Defendants deny the remaining allegations in this paragraph.

4. Defendants admit that Actavis Pharma, Inc. was formerly known as Watson Pharma, Inc. Defendants admit that Actavis Pharma, Inc. is a Delaware corporation having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054, and admit that Actavis Pharma is in the business of among other things, distributing and/or selling generic pharmaceutical products in the United States market, including products made by Actavis Laboratories FL, Inc. or for which Actavis Laboratories FL, Inc. is the applicant of an approved ANDA. Defendants deny the remaining allegations in this paragraph.

5. Defendants admit that Actavis, Inc. was formerly known as Watson Pharmaceuticals, Inc. until on or about January 24, 2013, admit that Actavis is a Nevada corporation having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054, and admit that Actavis Inc., through the actions of its subsidiaries, including Actavis Laboratories FL, Inc. and Actavis Pharma, among other things, develops, manufactures, obtains regulatory approval, markets, sells, and distributes generic pharmaceutical products in the United States market. Defendants deny the remaining allegations in this paragraph.

6. Defendants admit that Watson Pharmaceuticals acquired Andrx Pharmaceuticals on or about November 3, 2006, admit that Watson Pharmaceuticals renamed Andrx Pharmaceuticals as Watson Laboratories, Inc. – Florida, and admit that Watson Laboratories, Inc. – Florida was renamed as Actavis Laboratories FL, Inc.

7. Defendants admit that Actavis Laboratories FL, Inc. is a wholly owned subsidiary of Andrx Corporation, the latter of which is a wholly-owned subsidiary of Actavis, Inc. Defendants deny the remaining allegations in this paragraph.

8. Defendants admit the allegations in this paragraph.

9. Defendants admit that Actavis Inc. organized its operations by divisions and reports its financial results in its SEC filings by reference to its divisions. Defendants also admit that Actavis, Inc., formerly Watson Pharmaceuticals, Inc., has consolidated its financial results with its subsidiaries Actavis Laboratories FL, Inc. and Actavis Pharma since 2007, and did not file separate financial reports to the SEC for each subsidiary. Defendants deny the remaining allegations in this paragraph.

10. Defendants deny the allegations in this paragraph.

11. Defendants admit that the head of the Generics Division is an employee of Actavis Inc., and admit that Actavis Laboratories FL, Inc. submits ANDAs, and manufactures and develops generic pharmaceutical products for the U.S. market, and admits that Actavis Pharma sells and distributes generic pharmaceutical products in the U.S. market. Defendants also admit that Actavis Laboratories FL, Inc. and Actavis Pharma are parties to contractual agreements regarding generic pharmaceutical products. Defendants deny the remaining allegations in this paragraph.

12. Defendants admit that Actavis Laboratories FL, Inc., Actavis Pharma, and Actavis Inc. have a director and at least one officer in common. Defendants deny the remaining allegations in this paragraph.

13. Defendants for the purposes of this action only do not contest that Actavis Laboratories FL, Inc. and Actavis Pharma are within the control of Actavis, Inc. only for purposes of responding to discovery in this action. Defendants deny the remaining allegations in this paragraph.

### **BACKGROUND**

#### **The NDA**

14. Defendants lack knowledge and information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore deny same.

15. Defendants lack knowledge and information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore deny same.

#### **The Patents-In-Suit**

16. Defendants admit that United States Patent No. 8,852,636 (“the ‘636 patent”) is entitled “Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs” and states on

its face that it issued on October 7, 2014. Defendants admit that Exhibit A of Plaintiffs' Amended Complaint purports to be a copy of the '636 patent. Defendants lack knowledge and information sufficient to form a belief about the truth of the remaining allegations in this paragraph, and therefore deny same.

17. Defendants lack knowledge and information sufficient to form a belief about the truth of the in allegations this paragraph, and therefore deny same.

18. Defendants admit that the FDA Orange Book currently lists the '636 patent for Vimovo. Defendants lack knowledge and information sufficient to form a belief about the truth of the remaining allegations in this paragraph, and therefore deny same.

19. Defendants admit that United States Patent No. 8,858,996 ("the '996 patent") is entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs" and states on its face that it was issued on October 14, 2014. Defendants admit that Exhibit B of Plaintiffs' Amended Complaint purports to be a copy of the '996 patent. Defendants lack knowledge and information sufficient to form a belief about the truth of the remaining allegations in this paragraph, and therefore deny same.

20. Defendants lack knowledge and information sufficient to form a belief about the truth of the in allegations this paragraph, and therefore deny same.

21. Defendants admit that the FDA Orange Book currently lists the '996 patent for Vimovo. Defendants lack knowledge and information sufficient to form a belief about the truth of the remaining allegations in this paragraph, and therefore deny same.

22. Defendants admit that United States Patent No. 8,865,190 ("the '190 patent") is entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs" and states on its face that it was issued on October 21, 2014. Defendants admit that Exhibit C of Plaintiffs'

Amended Complaint purports to be a copy of the '190 patent. Defendants lack knowledge and information sufficient to form a belief about the truth of the remaining allegations in this paragraph, and therefore deny same.

23. Defendants lack knowledge and information sufficient to form a belief about the truth of the in allegations this paragraph, and therefore deny same.

**Related Patents**

24. Defendants admit that United States Patent No. 6,926,907 ("the '907 patent") is entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs" and states on its face that it was issued on August 9, 2005. Defendants deny the remaining allegations in this paragraph. Defendants lack knowledge and information sufficient to form a belief about the truth of the remaining allegations in this paragraph, and therefore deny same.

25. Defendants lack knowledge and information sufficient to form a belief about the truth of the in allegations this paragraph, and therefore deny same.

26. Defendants admit that the FDA Orange Book currently lists the '907 patent for Vimovo. Defendants lack knowledge and information sufficient to form a belief about the truth of the remaining allegations in this paragraph, and therefore deny same.

27. Defendants admit that United States Patent No. 8,557,285 ("the '285 patent") is entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs" and states on its face that it was issued on October 15, 2013. Defendants lack knowledge and information sufficient to form a belief about the truth of the remaining allegations in this paragraph, and therefore deny same.

28. Defendants lack knowledge and information sufficient to form a belief about the truth of the in allegations this paragraph, and therefore deny same.

29. Defendants admit that the FDA Orange Book currently lists the '285 patent for Vimovo. Defendants lack knowledge and information sufficient to form a belief about the truth of the remaining allegations in this paragraph, and therefore deny same.

**The ANDA**

30. Defendants admit that Actavis Laboratories FL, Inc. seeks the FDA's approval for the product that is the subject of ANDA No. 204470 ("the ANDA product"). Defendants deny the remaining allegations in this paragraph.

31. Defendants admit that by letter dated March 29, 2013, Actavis Laboratories FL, Inc. notified AstraZeneca AB and Pozen, Inc. that Defendants had filed ANDA No. 204470 seeking approval to market the product that is the subject of ANDA No. 204470 and that Defendants were providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 regarding certain patents including the '907 patent. Defendants deny the remaining allegations in this paragraph.

32. Defendants admit that by letter dated November 5, 2013, Actavis Laboratories FL, Inc. notified AstraZeneca AB and Pozen, Inc. that Defendants had filed ANDA No. 204470 seeking approval to market the product that is the subject of ANDA No. 204470 and that Defendants were providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 regarding certain patents including the '285 patent. Defendants deny the remaining allegations in this paragraph.

33. Defendants admit that by letter dated May 29, 2015, Actavis Laboratories FL, Inc. notified Horizon Pharma, Inc. and Pozen Inc. that Defendants had filed ANDA No. 204470 seeking approval to market the product that is the subject of ANDA No. 204470 and that Defendants were providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. §

314.95 regarding certain patents including the '636 and '996 patents. Defendants deny the remaining allegations in this paragraph.

### **JURISDICTION AND VENUE**

34. Defendants for purposes of this action only do not contest jurisdiction and venue. Defendants deny the remaining allegations in this paragraph.

35. Defendants admit that Actavis Laboratories FL, Inc. seeks the FDA's approval for the product that is the subject of ANDA No. 204470 ("The ANDA product"). Defendants deny the remaining allegations in this paragraph.

36. Defendants admit that the March ANDA Notice Letter states Actavis Laboratories FL, Inc.'s intention to seek FDA approval to market a generic version of the Vimovo product before the '907 patent expires. Defendants admit that the November ANDA Notice Letter states Actavis Laboratories FL, Inc.'s intention to seek FDA approval to market a generic version of the Vimovo® product before the '285 patent expires. Defendants deny the remaining allegations in this paragraph.

37. Defendants for purposes of this action only do not contest jurisdiction and venue. Defendants deny the remaining allegations in this paragraph.

38. Defendants for purposes of this action only do not contest jurisdiction and venue. Defendants deny the remaining allegations in this paragraph.

39. Defendants admit that Actavis Laboratories FL, Inc. filed a complaint in the U.S. District Court for the District of New Jersey (*Shionogi Inc. et al. v. Nostrum Labs., Inc. et al.*, C.A. No. 1:12-cv-04402-RBK-JS (D.I. 1)) and asserting counterclaims in this Court (in *Depomed, Inc. v. Actavis Elizabeth LLC et al.*, C.A. No. 3:12-cv-01358-JAPTJB (D.I. 47) and in

*AstraZeneca AB et al. v. Actavis Laboratories FL Inc. et al.*, C.A. No. 3:13- cv-03038-JAP-DEA (D.I. 54)). Defendants deny the remaining allegations in this paragraph.

40. Defendants deny the allegations in this paragraph.

41. Defendants deny the allegations in this paragraph.

42. Defendants admit that Actavis Laboratories FL, Inc. participated in the preparation and/or filing of ANDA No. 204470. Defendants deny the remaining allegations in this paragraph.

43. Defendants deny the allegations in this paragraph.

44. Defendants for purposes of this action only do not contest personal jurisdiction. Defendants deny the remaining allegations in this paragraph.

45. Defendants for purposes of this action only do not contest venue. Defendants deny the remaining allegations in this paragraph.

**COUNT I**  
**(INFRINGEMENT OF THE '636 PATENT UNDER 35 U.S.C. § 271(e)(2))**

46. Defendants incorporate by reference their responses to the allegations in paragraphs 1-45.

47. The allegations in this paragraph constitute legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

48. The allegations in this paragraph constitute legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

49. The allegations in this paragraph constitute legal conclusions to which no response is required. To the extent a response is required, Defendants admit that the cited

statutory language has been quoted accurately. Defendants deny the remaining allegations in this paragraph.

50. Defendants deny the allegations in this paragraph.

51. Defendants admit that they continue to seek final FDA approval of the product contained in ANDA No. 204470. Defendants deny the remaining allegations in this paragraph.

52. Defendants deny the allegations in this paragraph.

53. Defendants deny the allegations in this paragraph.

54. Defendants deny the allegations in this paragraph.

55. Defendants deny the allegations in this paragraph.

56. Defendants deny the allegations in this paragraph.

57. Defendants deny the allegations in this paragraph.

**COUNT II**  
**(DECLARATORY JUDGMENT AS TO THE '636 PATENT)**

58. Defendants incorporate by reference their responses to the allegations in paragraphs 1-57.

59. The allegations in this paragraph constitute legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

60. Defendants deny the allegations in this paragraph.

61. Defendants deny the allegations in this paragraph.

62. Defendants admit that they continue to seek final FDA approval of the product contained in ANDA No. 204470. Defendants deny the remaining allegations in this paragraph.

63. Defendants deny the allegations in this paragraph.

64. Defendants deny the allegations in this paragraph.

65. Defendants deny the allegations in this paragraph.

66. Defendants admit that they continue to seek final FDA approval of the product contained in ANDA No. 204470. Defendants deny the remaining allegations in this paragraph.

67. Defendants admit that they maintain that the '636 patent is invalid or unenforceable and that Actavis' ANDA Product does not or will not infringe the '636 patent. Defendants state that for purposes of this action only Defendants do not contest jurisdiction and venue. Defendants deny the remaining allegations in this paragraph.

68. Defendants deny the allegations in this paragraph.

69. Defendants deny the allegations in this paragraph.

**COUNT III**  
**INFRINGEMENT OF THE '996 PATENT UNDER 35 U.S.C. § 271(e)(2)**

70. Defendants incorporate by reference their responses to the allegations in paragraphs 1-69.

71. The allegations in this paragraph constitute legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

72. The allegations in this paragraph constitute legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

73. The allegations in this paragraph constitute legal conclusions to which no response is required. To the extent a response is required, Defendants admit that the cited statutory language has been quoted accurately. Defendants deny the remaining allegations in this paragraph.

74. Defendants admit the allegations in this paragraph.

75. Defendants admit that they continue to seek final FDA approval of the product contained in ANDA No. 204470. Defendants deny the remaining allegations in this paragraph.

76. Defendants deny the allegations in this paragraph.

77. Defendants deny the allegations in this paragraph.

78. Defendants deny the allegations in this paragraph.

79. Defendants deny the allegations in this paragraph.

80. Defendants deny the allegations in this paragraph.

81. Defendants deny the allegations in this paragraph.

**COUNT IV**  
**(DECLATORY JUDGMENT AS TO THE '996 PATENT)**

82. Defendants incorporate by reference their responses to the allegations in paragraphs 1-81.

83. The allegations in this paragraph constitute legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

84. Defendants deny the allegations in this paragraph.

85. Defendants deny the allegations in this paragraph.

86. Defendants admit that they continue to seek final FDA approval of the product in ANDA No. 204470. Defendants deny the remaining allegations in this paragraph.

87. Defendants deny the allegations in this paragraph.

88. Defendants admit that they continue to seek final FDA approval of the product contained in ANDA No. 204470. Defendants deny the remaining allegations in this paragraph.

89. Defendants deny the allegations in this paragraph.

90. Defendants admit that they continue to seek final FDA approval of the product contained in ANDA No. 204470. Defendants deny the remaining allegations in this paragraph.

91. Defendants admit that they maintain that the '996 patent is invalid and that Actavis' ANDA Product does not or will not infringe the '996 patent. Defendants state that for purposes of this action only Defendants do not contest jurisdiction and venue. Defendants deny the remaining allegations in this paragraph.

92. Defendants deny the allegations in this paragraph.

93. Defendants deny the allegations in this paragraph.

**COUNT V**  
**(DECLATORY JUDGMENT AS TO THE '190 PATENT)**

94. Defendants incorporate by reference their responses to the allegations in paragraphs 1-93.

95. The allegations in this paragraph constitute legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in this paragraph.

96. Defendants deny the allegations in this paragraph.

97. Defendants deny the allegations in this paragraph.

98. Defendants admit that they continue to seek final FDA approval of the product contained in ANDA No. 204470. Defendants deny the remaining allegations in this paragraph.

99. Defendants deny the allegations in this paragraph.

100. Defendants admit that they continue to seek final FDA approval of the product contained in ANDA No. 204470. Defendants deny the remaining allegations in this paragraph.

101. Defendants deny the allegations in this paragraph.

102. Defendants admit that they continue to seek final FDA approval of the product contained in ANDA No. 204470. Defendants deny the remaining allegations in this paragraph.

103. Defendants for purposes of this action only do not contest jurisdiction and venue. Defendants deny the remaining allegations in this paragraph.

104. Defendants deny the allegations in this paragraph.

105. Defendants deny the allegations in this paragraph.

### **PRAYER FOR RELIEF**

Defendants deny that Plaintiffs are entitled to the relief requested in paragraphs (A) – (J).

### **DEFENSES**

Without prejudice to the denials set forth above, Defendants assert the following defenses:

#### **FIRST DEFENSE** **(Non-Infringement)**

Defendants do not infringe, induce the infringement of, or contribute to the infringement of any valid and enforceable claim of the '636, '996, and '190 patents.

#### **SECOND DEFENSE** **(Invalidity)**

The claims of the '636, '996, and '190 patents are invalid for failure to satisfy the provisions of the United States Code, including but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112.

#### **THIRD DEFENSE** **(Failure to State a Claim)**

The Complaint is subject to dismissal for failure to state a claim upon which relief may be granted.

### **COUNTERCLAIMS**

Defendant/Counterclaimant Actavis Laboratories, FL., Inc., hereby asserts counterclaims against Plaintiffs/Counterdefendants Horizon Pharma, Inc. and Pozen, Inc., as follows:

### **PARTIES**

1. Actavis Laboratories, FL., Inc. is a Florida corporation having a place of business at 4955 Orange Drive, Davie, Florida 33314.

2. Upon information and belief, Horizon Pharma, Inc. (“Horizon”) is a Delaware corporation having its principal place of business at 520 Lake Cook Road, Suite 520, Deerfield, Illinois 60015.

3. Upon information and belief, Pozen, Inc. (“Pozen”) is a Delaware corporation having its principal place of business at 1414 Raleigh Road, Chapel Hill, North Carolina 27517.

### **JURISDICTION AND VENUE**

4. These counterclaims seek a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.

5. The Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1138(a), 2201, and 2202, and 35 U.S.C. §§ 271(e)(2) and (e)(5).

6. The Court has personal jurisdiction over Counterdefendants on the basis of, *inter alia*, their contacts with the District of New Jersey relating to the subject matter of this action, including having filed this action.

7. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), and by Counterdefendants’ choice of forum.

### **BACKGROUND**

8. This is an action based upon an actual controversy between the parties concerning Actavis Laboratories FL, Inc.'s right to continue to seek FDA approval of ANDA No. 204470, and upon approval, to manufacture, import, use, market, sell, and/or offer to sell in the United States the product that is the subject of ANDA No. 204470 ("the ANDA product").

9. Counterdefendants allege that the manufacture, importation, use, marketing, sale and/or offer to sell in the United States of the ANDA product infringes the '636, '996, and '190 patents.

10. The '636 and '996 patents, in addition to U.S. Patent No. 8,945,621 ("the '621 patent"), are listed in the FDA's Approved Drug Products with Therapeutic Equivalence ("the Orange Book") for the drug Vimovo.

11. The FDA website identifies Horizon Pharma, Inc. as the applicant for NDA No. 022511, which relates to Vimovo.

12. One or more of the Counterdefendants caused the '636, '996, and '621 patents to be listed in the Orange Book in association with Vimovo.

13. As a consequence of listing the '636, '996, and '621 patents in the Orange Book, one or more of the Counterdefendants were and are representing to the world that the '636, '996, and '621 patents claim Vimovo and its active ingredients, and that patent infringement actions relating to the '636, '996, and '621 patents could reasonably be expected to be brought against unlicensed filers of ANDAs for which patent certification would be required.

14. Actavis Laboratories FL, Inc. certified to the FDA in its ANDA No. 204470 that, in Actavis Laboratories FL, Inc.'s opinion and to the best of its knowledge, the ANDA product will not infringe any valid, enforceable claim of the '636, '996, and '621 patents.

15. Actavis Laboratories FL, Inc., Inc., notified Counterdefendants Horizon and Pozen, of the factual and legal bases for Actavis' certification with respect to the '636, '996 and '621 patents in a letter dated May 29, 2015 ("the May 2015 Notice Letter").

16. Counterdefendants have filed this action to enforce the '636, '996, and '190 patents. Counterdefendants did not assert in this action any claims against Counterclaimant with respect to the '621 patent.

17. In response to the Complaint, Counterclaimant has denied that it has, does, or will infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '636, '996, and '190 patents.

18. In response to the Complaint, Counterclaimant has further asserted that the '636, '996, and '190 patents are invalid for failure to satisfy the provisions of the United States Code, including but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112.

19. A definite, concrete, real, substantial, and justiciable controversy exists between Counterclaimant and Counterdefendants with respect to the validity and infringement of the '636, '996, '190 and '621 patents, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

**FIRST COUNTERCLAIM**  
**(Declaratory Judgment of Non-Infringement)**

20. Counterclaimant incorporates by reference its allegation in paragraphs 1-19 of these Counterclaims.

21. Counterclaimant does not infringe any valid and enforceable claim of the '636, '996, '190, and '621 patents, either directly, indirectly, literally, or under the doctrine of equivalents.

22. The sale, offer for sale, manufacture, importation, or use of the ANDA product will not constitute infringement of any valid and enforceable claim of the '636, '996, '190, and '621 patents, either directly, indirectly, literally, or under the doctrine of equivalents.

**SECOND COUNTERCLAIM**  
**(Declaratory Judgment of Invalidity)**

23. Counterclaimant incorporates by reference its allegations in paragraphs 1-22 of these Counterclaims.

24. The claims of the '636, '996, '190 and '621 patents are invalid for failure to satisfy the provisions of the United States Code, including but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112.

**PRAYER FOR RELIEF**

WHEREFORE, Counterclaimant prays for the following relief:

A. That all claims against Defendants be dismissed with prejudice, that all relief requested by Plaintiffs be denied, and that Plaintiffs take nothing by their Complaint;

B. That a judgment be entered declaring that Counterclaimant has not and does not infringe any valid and enforceable claim of the '636, '996, '190, and '621 patents, either directly, indirectly, literally, or under the doctrine of equivalents; that Counterclaimant has a lawful right to obtain FDA approval of ANDA No. 204470; and further that Counterclaimant has a lawful right once approved by the FDA to manufacture, import, use, sell, and offer to sell the ANDA product in the United States;

C. That a judgment be entered declaring that the claims of the '636, '996, '190, and '621 patents are invalid for failure to satisfy the provisions of the United States Code, including but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112;

D. That Counterdefendants, their parents, subsidiaries, agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice thereof, be preliminarily and permanently enjoined from threatening or initiating infringement litigation against the Counterclaimant or any of its customers, dealers, or supplier, or any protective or present sellers, dealers, distributors, or customers, or charging any of them either orally or in writing, with infringement of the '636, '996, '190 and '621 patents;

E. That a judgment be entered declaring that this action is an exceptional case within the meaning of 35 U.S.C. § 285 and that Counterclaimant is entitled to recover its reasonable attorneys' fees upon prevailing in this action;

F. That Counterclaimant be awarded its costs, attorneys' fees, and other relief, both legal and equitable, to which they may be entitled; and

G. That Counterclaimant be awarded such other and further relief as is just and proper.

Dated: July 20, 2015

By: /s/ Robert J. Fettweis  
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*Attorneys for Defendants Actavis  
Laboratories FL, Inc., Actavis Pharma, Inc.  
and Actavis, Inc.*

**LOCAL CIVIL RULE 11.2 CERTIFICATION**

The matter in controversy is the subject of the following actions:

HORIZON, PHARMA et al. v. ACTAVIS LABORATORIES FL, INC. et al., C.A. No. 13-cv-03038-JAP-DEA (D.N.J.)

HORIZON PHARMA, INC. et al. v. DR. REDDY'S LABS, INC., et al., C.A. No. 3:11-cv-02317-JAP-DEA (D.N.J.);

HORIZON PHARMA, INC. et al. v. DR. REDDY'S LABS, INC., et al., C.A. No. 3:13-cv-00091-JAP-DEA (D.N.J.);

HORIZON PHARMA, INC. et al. v. LUPIN LTD., et al., C.A. No. 3:11-cv-04275-JAP-DEA (D.N.J.);

HORIZON PHARMA, INC. et al. v. MYLAN PHARMACEUTICALS et al., C.A. No. 3:13-cv-04022-JAP-DEA (D.N.J.);

Dated: July 20, 2015

By: /s/ Robert J. Fettweis  
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*Attorneys for Defendants  
Actavis Laboratories FL, Inc.,  
Actavis Pharma, Inc. and Actavis, Inc.*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

HORIZON PHARMA, INC. and POZEN  
INC.,

Plaintiffs,

Vs.

ACTAVIS LABORATORIES FL., INC.,  
ACTAVIS PHARMA, INC., and ACTAVIS  
INC.,

Defendants.

**ELECTRONICALLY FILED  
DOCUMENT**

Civil Action No. 3:15-cv-03322-MLC-DEA

**CERTIFICATE OF SERVICE AND  
FILING**

I certify that I caused electronic copies of Defendants Actavis Laboratories FL, Inc., Actavis Pharma, Inc. and Actavis Inc.'s Answer, Defenses and Counterclaims and this Certificate of Service to be electronically filed and served today in accordance with the electronic case filing policies and procedures on William T. Walsh, Clerk, United States District Court, District of New Jersey, Clarkson S. Fisher Building & U.S. Courthouse, 402 East State Street, Trenton, New Jersey 08608.

I also certify that on this date I caused one copy of the above to be served via ECF and via e-mail on counsel of record.

I hereby that the foregoing statements made by me are true. I am aware that if any of the foregoing statement made by me are willfully false, I am subject to punishment.

Dated: July 20, 2015

By: /s/ Robert J. Fettweis  
Robert J. Fettweis

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